

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jan 2020

### The effect of valerian on cognitive disorders in hemodialysis' patients

#### Protocol summary

##### Summary

Objective: To determine the effect of valerian on cognitive disorders in hemodialysis' patients. Inclusion criteria: Over 18 years of age; hemodialysis 3 times a week for 3 hours; for more than 3 months; full consciousness; hearing and speech ability; and not having sensitivity to plants. Exclusion criteria: Physical or mental disability; drug abuse; cancer; hearing or visual disorder; experienced recent stressful event; kidney transplant; acute illness; body mass index over 30; liver disease; hepatitis; cirrhosis; travel; or death of the patient. Population under Study: Hemodialysis' patients of Kowsar in Semnan, 15 Khordad in Mahdishahr and Emam in Garmsar hospitals. Sample size: A pilot study including 30 patients, would determine the size of samples. First intervention: Group A use Valerian capsules (Sedamin 530 mg, Goldaru Co.) 60 minutes before bedtime for one month. After one month cleaning, group A will receive placebo. Completion of MMSE questionnaires and EEG (day after hemodialysis) is done before and after each intervention. Second intervention: Group B uses placebo capsules (starch 50 mg, Goldaru Co.) 60 minutes before bedtime for one month. After one month cleaning, group B will receive Valerian capsules (Sedamin 530 mg, Goldaru Co.). Completion of MMSE questionnaires and EEG (day after hemodialysis) is done before and after each intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201606076318N7**  
 Registration date: **2016-06-17, 1395/03/28**  
 Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-06-17, 1395/03/28

##### Registrant information

##### Name

Monir Nobahar

##### Name of organization / entity

Semnan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3365 4190

##### Email address

nobahar43@sem-ums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Semnan University of Medical Sciences

##### Expected recruitment start date

2016-05-26, 1395/03/06

##### Expected recruitment end date

2016-10-27, 1395/08/06

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of valerian on cognitive disorders in hemodialysis' patients

##### Public title

The effect of valerian on cognitive disorders in hemodialysis' patients

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Over 18 years of age; hemodialysis 3 times a week for 3 hours; for more than 3 months; full consciousness; hearing and speech ability; and not having sensitivity to plants. Exclusion criteria: Physical or mental disability; drug abuse; cancer; hearing or visual disorder; experienced recent stressful event; kidney transplant; acute illness; body mass index over 30; liver disease; hepatitis; cirrhosis; travel; or death of the patient.

##### Age

No age limit

##### Gender

Both

##### Phase

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **30****Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees**1**Ethics committee****Name of ethics committee**

Semnan University of Medical Sciences

**Street address**Nursing and Paramedical Faculty, University of  
Medical Sciences, Semnan**City**

Semnan

**Postal code****Approval date**

2016-05-25, 1395/03/05

**Ethics committee reference number**

IR.SEMUMS.REC.1395.25

**Health conditions studied**1**Description of health condition studied**

Hemodialysis patients

**ICD-10 code**

F02.8

**ICD-10 code description**

Dementia in other specified diseases classified elsewhere

**Primary outcomes**1**Description**

Cognitive status

**Timepoint**Before the intervention, one month after the first  
intervention, one month after the cleansing and one  
month after the second intervention**Method of measurement**In this study, Cognitive status is measured by using  
Electroencephalography (EEG) and MMSE questionnaire.

This measurement is performed within three consecutive months (before the intervention, one month after the first intervention, one month after the cleansing and one month after the second intervention). The score for total cognitive health is (25-30), for mild cognitive disorder is (21-24), for moderate disorder is (10-20) and for severe disorder is (<9). Information for each person will be recorded in their personal questionnaire.

**Secondary outcomes**

empty

**Intervention groups**1**Description**

Group A uses Valerian capsules (Sedamin 530 mg, Goldaru Co.) 60 minutes before bedtime for one month. After one month (cleaning or wash out), the type of treatment between two groups is replaced, group A will receive placebo. Completion of Mini Mental State Examination (MMSE) questionnaires and EEG (day after hemodialysis) is done before and after each intervention.

**Category**

N/A

2**Description**

Group B uses placebo capsules (starch 50 mg, Goldaru Co.) 60 minutes before bedtime for one month. After one month (cleaning or wash out), the type of treatment between two groups is replaced, group B will receive Valerian capsules (Sedamin 530 mg, Goldaru Co.). Completion of Mini Mental State Examination (MMSE) questionnaires and EEG (day after hemodialysis) is done before and after each intervention.

**Category**

N/A

**Recruitment centers**1**Recruitment center****Name of recruitment center**Kowsar in Semnan, Khordad The 15th in Mahdishahr  
and Emam in Garmsar**Full name of responsible person**

Monir Nobahar

**Street address**Faculty Nursing and Paramedical, Semnan University  
of Medical Sciences, Semnan**City**

Semnan

**Sponsors / Funding sources**

**1****Sponsor****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Dr. Ali Rashidypour

**Street address**

Faculty Nursing and Paramedical, Semnan University of Medical Sciences, Semnan

**City**

Semnan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Semnan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Monir Nobahar

**Position**

Associate Professor of Semnan University of Medical Sciences

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*